



Australian Government

Australian Quarantine and Inspection Service

Approved Laboratory Program

(Export meat and meat products)

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1 Introduction

Meat has been identified as a vehicle for a significant proportion of human foodborne disease with a number of important foodborne disease agents being found on meat including enterohaemorrhagic *Escherichia coli*, *Salmonella* spp. and *Campylobacter jejuni*. Inspection and food safety programs associated with meat production serve two functions, to assess animal health and to control or eliminate zoonoses that impact on public health.

Microbiological monitoring programs are in place in Australia. Industry based programs verify the day to day operations at individual establishments and generally use indicator organisms to assess hygienic performance. Testing carried out to meet regulatory requirements, such as that carried out as part of the *E. coli* / *Salmonella* monitoring (ESAM) program verifies industry food safety control programs and provides data to enable AQIS to demonstrate equivalence to food safety programs in different countries. To ensure the validity of the result obtained from regulatory based testing, AQIS has implemented an approved laboratory program (ALP). The ALP ensures that laboratories participating in regulatory testing programs apply internationally accepted principles to ensure the quality and accuracy of results.

2 General Information

2.1 Scope

The ALP is an integral part of the system that AQIS has in place to enable market access. The program applies to laboratories undertaking microbiological testing of edible meat and meat products required to fulfil export requirements for AQIS certification. It includes on-plant and commercial laboratories. This includes all testing undertaken as part of the ESAM program and microbiological testing requirements specified in Volume 2 of the Export Meat Manual (available from AQIS). The program only applies to microbiological testing relied on for AQIS certification.

2.2 Eligible Laboratories

All laboratories, both on-plant and commercial, that can meet the requirements of the program are eligible to be included on the approved laboratory list. There are no limits on the number of approved laboratories.

3 Laboratory Approval

3.1 Application

3.1.1 Laboratories seeking to be recognised as an approved laboratory must make a written application to: Approved Laboratory Program, Food Export Branch, Food Division, Biosecurity Services Group, GPO Box 858, Canberra ACT

2601 or MID.OpsCord@aqis.gov.au, using the form in Annex 1 of this document.

- 3.1.2 All laboratories seeking to be recognised as approved laboratories must make available any documentation that AQIS requests to verify the testing methods used by the laboratory and, if applicable, the laboratories performance in past assessments by NATA.
- 3.1.3 Applications should include:
- The laboratory's scope of accreditation (if applicable to the relevant testing program);
 - Details of approved methods that the laboratory intends to use for the testing of meat and meat products (with appropriate accreditation documentation if applicable);
 - Agreement to participate in proficiency testing programs;
 - An application form signed by an authorised company representative.
- 3.1.4 Following written notification of approval of the application (by a desk audit) the laboratory will be granted approval to test meat and meat product as part of an export certification program. Laboratories must receive written advice from AQIS before commencing testing. An on-site assessment of the laboratory may be required prior to approval.

3.2 Maintaining Approval

- 3.2.1 In order to remain an approved laboratory, a laboratory must meet the requirements specified in this document and any other document specified by AQIS. This includes but is not limited to:
- maintenance of accreditation for the specified approved methods (if applicable to the relevant testing program);
 - Annual assessment by AQIS or NATA;
 - Participation in proficiency testing rounds as required/recommended by NATA and/or AQIS (minimum 6-monthly).
- 3.2.2 An approved laboratory can identify itself as an approved laboratory for the purpose of testing meat and meat products for export certification.
- 3.2.3 A laboratory must never make or imply that being an approved laboratory is an endorsement by AQIS of its performance in relation to testing outside the testing carried out under the ALP.
- 3.2.4 The laboratory will remain an approved laboratory until it requests to be removed from the list or until such time as the laboratory is removed from the list by AQIS.
- 3.2.5 Any request by the laboratory to change the conditions or scope of its approval/accreditation must be made in writing to AQIS or NATA as appropriate. AQIS will then consider changes to the laboratory's scope of approval.
- 3.2.6 Approved laboratories must notify AQIS of any changes in their scope of accreditation or any other changes that may reasonably be expected to impact on the competency of the laboratory in relation to tests carried out as part of an export certification program.

3.3 Reporting results to AQIS

- 3.3.1 Approved laboratories must report all test results that are relevant to export certification programs to AQIS at the same time that they are reported to management at the export establishment.
- 3.3.2 Where particular aspects of testing are contracted to another approved laboratory the contracting laboratory must notify the contracted laboratory of the requirements to report results directly to AQIS.
- 3.3.3 Results must be reported as soon as possible (generally within 24 h) after completion of the analytical test. Presumptive positive samples for *E. coli* O157:H7 and *Listeria monocytogenes* should be reported to AQIS and the company before confirmation so that implicated production lots can be identified and retained or controlled.

3.4 Suspension/Revocation of Approval

- 3.4.1 AQIS may suspend or remove a laboratory from the ALP if NATA notifies AQIS that the laboratory has not satisfactorily implemented corrective actions identified as part of the laboratory's annual assessment.
- 3.4.2 AQIS may suspend or remove a laboratory from the ALP if it does not meet all the requirements of an approved laboratory.
- 3.4.3 AQIS may suspend or remove a laboratory from the ALP if it considers that a laboratory is not competent in any aspect of its work that would reasonably be expected to impact on the reliability of test results.

3.5 Procedure for Suspension/Revocation of Approval

- 3.5.1 On notification from AQIS of suspension or removal of a laboratory from the ALP, the laboratory must immediately cease all testing relating to export certification and notify relevant customers (i.e. export establishments) of its suspension or removal.
- 3.5.2 In order for the laboratory to be reinstated as an approved laboratory it must meet all conditions specified by AQIS or NATA in relation to its suspension/removal and re-apply for consideration as an approved laboratory following the procedures set out in this document.

4 Assessment/Accreditation

Laboratories testing meat and meat products relevant to AQIS certification should be accredited by NATA to undertake such testing and as meeting ISO/IEC 17025. Laboratories not accredited by NATA may also be recognised as approved laboratories by AQIS to undertake specific testing if they comply with the requirements set out in Annex 2.

4.1 Accreditation Body

- 4.1.1 AQIS recognises the National Association of Testing Authorities, Australia (NATA) as the Australian authority for accrediting laboratories for testing. NATA is a private, not-for-profit company, governed by its members and representatives from industry, government and professional bodies. NATA represents Australia in the International Laboratory Accreditation Cooperation

(ILAC), the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and is the Good Laboratory Practice (GLP) compliance monitoring authority representing Australia on the OECD GLP Working Group. NATA has a Memorandum of Understanding with the Australian Commonwealth Government and the relationship between NATA and AQIS is defined in a Deed of Agreement.

- 4.1.2 NATA accreditation requires laboratories to meet Australian Standard ISO/IEC 17025:2005 “General requirements for the competence of testing and calibration laboratories” and ISO/IEC 17025 Application Document (Supplementary Requirements for Accreditation) must form the basis for assessment/accreditation purposes;
- 4.1.3 Requirements for laboratories that are not accredited by NATA are summarised in Annex 2.
- 4.1.4 ALP requirements include assessment of management systems, quality programs and nominated technical requirements as specified by AQIS;
- 4.1.5 Laboratories must maintain their accreditation/approval and ensure that staff have appropriate qualifications;
- 4.1.6 Assessment will be carried out on laboratories
 - Annually by NATA or AQIS
 - Whenever NATA or AQIS deems it necessary
- 4.1.7 Assessments may be carried out by third parties such as importing country reviewers

4.2 AQIS assessments

- 4.2.1 AQIS will undertake assessments of approved laboratories over a one to four year period depending on the type of testing involved and NATA accreditation. Laboratories that do not have NATA accreditation will be assessed annually by AQIS¹;
- 4.2.2 AQIS assessments will generally be in conjunction with a scheduled NATA assessment, although ‘AQIS only’ assessments may also be undertaken;
- 4.2.3 For ‘AQIS only’ assessments a minimum of one weeks notice will be given of assessments where possible and may include participation by importing country reviewers;
- 4.2.4 AQIS assessments will focus on quality systems and approved methods.
- 4.2.5 NATA or AQIS will notify the laboratory of the date of assessment prior to the visit;
- 4.2.6 The laboratory must make available, on request by NATA or AQIS, all documents relevant to the laboratory’s participation in the ALP, including proficiency testing reports.;
- 4.2.7 A technical assessor may be appointed by NATA or AQIS to help with the assessment. In such a case the technical assessor will be provided with such documentation as necessary to perform their task. Only records relevant to the technical assessor’s responsibilities are to be provided to the technical

¹ In special cases where standard accreditation procedures are not applicable or where laboratories are undertaking testing that is not accredited by NATA, AQIS may allow alternative procedures for assessment to be used. An example might be research laboratories employing specialised techniques that are used infrequently.

assessor. All documentation will be held in confidence and returned to NATA or AQIS on completion of the assessment;

- 4.2.8 The laboratory has the right to challenge individual technical assessors on the grounds of conflict of interest. NATA or AQIS will deal with such situations according to their standard procedures.

4.3 On-site assessment

- 4.3.1 Information on the performance of the laboratory will be collected through interviews with staff, examination of documents/records and observation;
- 4.3.2 Assessors can request to observe laboratory staff while performing routine tests;
- 4.3.3 Where applicable all signatories for tests included in the assessment are to be available on the day unless otherwise agreed to by NATA;
- 4.3.4 Where sample collection is part of the laboratory's scope the assessors must review;
- The procedure for identifying samples for testing, training records and approval for individuals undertaking sample collection, including non-laboratory staff involved in sampling;
 - A nominated AQIS officer may arrange for a special partial assessment of any or all sample collection programs (relating to testing for export certification) when sampling is not part of the laboratory's scope.

4.4 Assessors

- 4.4.1 The Lead Assessor must be a full time employee of NATA or AQIS and familiar with all requirements of the ALP.
- 4.4.2 Technical Assessor
- Technical assessors must have the following minimum qualifications;
 - Tertiary qualifications (or equivalent practical experience) in the field relevant to the scope of accreditation of the laboratory being assessed i.e. biological testing.
 - A least five years experience working in laboratories with a similar scope of accreditation to the laboratory being assessed and be able to demonstrate a high degree of competency.
 - Technical assessors must not have any association with the laboratory that might be perceived as influencing the assessment or that could be seen as a conflict of interest. Any association or conflict of interest must be recorded with the list of technical assessors.

4.5 Assessment Findings

- 4.5.1 Assessment findings must be discussed with the laboratory's authorised representative on the day of the assessment, including reference to all non-conformities and applicable requirements.
- 4.5.2 Corrective action requests must be issued in accordance with the requirements of NATA or AQIS's documented procedures and include a time frame in which the laboratory is required to demonstrate that the corrective action has been implemented.

- 4.5.3 Assessment findings will generally follow an informal ranking procedure agreed to by the Lead Assessor and the Technical Assessor. Non-conformities and observations should be ranked as follows;
- Observation (O) - May simply be an observation or a recommendation or a reminder or flag for follow-up/review at the next assessment;
 - Minor Condition (M) - Description of the action taken or intended must be provided in the time negotiated for response. Supporting evidence of this action will not be required as it will be reviewed at the next assessment. The laboratory is encouraged to include the Minor Condition in their corrective action and internal audit program;
 - Condition (C) - Response on action taken is required with supporting evidence of this action. This must be provided in the time that has been negotiated for response.

4.6 Assessment Reports

- 4.6.1 A final reviewed report will be provided to the laboratory as soon as possible after the assessment.
- 4.6.2 Laboratories must ensure that they;
- Take the required corrective actions within the agreed time frame;
 - Provide NATA or AQIS with supporting documentation demonstrating that corrective actions have been addressed.
- 4.6.3 NATA must ensure that it;
- Provides AQIS with copies of the assessment report noting conditions and laboratory response on corrective actions;
 - Ensures that corrective actions are carried out by the laboratory in the agreed time frame;
 - Provide AQIS, on request, with any supporting documentation provided by laboratories in relation to corrective actions.
- 4.6.4 NATA or AQIS may extend the time allowed for corrective actions but only under special circumstances and where NATA or AQIS is satisfied that progress is being made in implementing corrective actions and that the non-conformity will not impact on the reliability of analytical test results.

4.7 Follow up Assessment

- 4.7.1 Follow-up on-site assessments may be required to verify the implementation of corrective actions that have arisen as a result of the outcomes of the assessment.
- 4.7.2 The time frame for follow-up assessments will be discussed with the laboratory at the time of the assessment.
- 4.7.3 Follow-up assessments can be undertaken by AQIS either to verify corrective actions or to confirm NATA's on-going competency.
- 4.7.4 Follow-up assessment reporting will follow the same protocols as outlined in section 4.

5 Laboratory Methods/Tests

5.1 Sampling

Sample collection is generally outside the scope of accreditation of commercial laboratories. However, all approved laboratories must ensure that the condition of samples on arrival at the laboratory is consistent with the requirements of the specific program to which they apply (e.g. ESAM).

- 5.1.1 Where sample collection is part of the laboratory's accreditation/approval the laboratory must ensure that it is carried out according to the technical requirements for the program .
- 5.1.2 Laboratories must ensure that sampling carried out for specific programs is undertaken by trained persons and must keep appropriate training records.
- 5.1.3 AQIS on-plant personnel must supervise sampling carried out on-plant for specific programs.

5.2 Approved Methods

An integral part of the ALP is the use of standard microbiological methods for the analysis of meat and meat products. This is necessary to ensure that equivalence with markets is maintained. Approved methods must be used for testing meat and meat products as part of an export certification program.

- 5.2.1 Approved methods are published on the AQIS web site and can be obtained from AQIS on request. The list will include an outline and specific checklist for each method.
- 5.2.2 Approved methods must be followed without modification, unless such modifications have been agreed to by AQIS and are under the laboratory's scope of accreditation/approval.
- 5.2.3 Any approved laboratory may undertake testing using approved methods if their scope of accreditation/approval includes the specific tests to be used and the method is included in their annual assessment by NATA or AQIS. Laboratories must notify AQIS of any changes to approved methods used by the laboratory for testing of as part of export certification before implementing the methods.
- 5.2.4 Laboratories may 'contract out' specific aspects of testing, including confirmation of presumptive positive samples, however contracted laboratories must be approved laboratories, must be acknowledged on the report of test results and must be instructed to report results to AQIS at the same time that they are reported to the contracting laboratory.

5.3 Variations to the List of Approved Methods

From time to time AQIS will revise the approved methods list and add and delete methods as appropriate.

- 5.3.1 New methods can be submitted to AQIS for consideration as approved methods.
- 5.3.2 Methods accredited by standards organisations or governments will not automatically be added to the approved methods list. The following points will be considered;

- The methods must be suitable for the test under consideration;
 - Methods should be validated according to ISO 1614:2003 or by an internationally recognised certifying body such as the AOAC or AFNOR (spell out both acronyms).
 - Methods used as national standards in a country may be considered for approval, with the proviso that such methods can only be used for testing as part of a certification program for export to that country.
- 5.3.3 AQIS will put new methods forward to importing countries for approval as appropriate to ensure maintenance of markets.
- 5.3.4 The time frame for consideration of new methods is dependent on the above factors and cannot be estimated. Methods cannot be used unless they are approved.

6 Proficiency Testing (PT) Program

The primary purpose of proficiency testing is to assess a laboratory's ability to competently perform tests for which AQIS approval is held. Proficiency testing also provides an additional external audit of a laboratories testing capability and is a useful training tool.

6.1 PT Providers

Proficiency testing providers must:

- be accredited to ILAC G13:2000 'Guidelines for the requirements for the Competence of Providers of Proficiency Testing Schemes';
- ensure that PT samples are appropriate for the field of testing;
- maintain a quality assurance program that measures both the homogeneity and stability of the samples;
- provide laboratories with clear instructions on how the test must be performed;
- provide timely reports to all participating laboratories;

6.2 Participation in PT Programs

- 6.2.1 Approved laboratories are required to participate in PT programs that relate directly to tests included in their scope;
- 6.2.2 The minimum frequency for participation in PT programs is specified by NATA or AQIS and is typically 6-monthly.
- 6.2.3 Laboratories approved for multiple tests for a single analyte must have a written procedure for ensuring all test methods are regularly included in the appropriate PT program. In the case of multiple methods the minimum frequency referred to in 6.2.2 will be based on the analyte.

6.3 Performance

- 6.3.1 Performance criteria will be established in line with the policies of the PT provider. Performance measures will include;

- information on the laboratory's results in relation to the "central" or median result for each sample;
 - identification of outliers/false negatives;
 - false positive results where applicable;
 - accuracy of calculations.
- 6.3.2 The PT provider will inform the laboratory of results it deems to be inadequate i.e. results that fall outside the set tolerance interval established for that round of testing.
- 6.3.3 Laboratories must immediately notify AQIS or NATA of non-conforming results.
- 6.3.4 AQIS and NATA will review the laboratory's response and either;
- Accept that the problem has been rectified, this will require the laboratory to submit documented evidence to support any corrective action taken;
 - Take further action as appropriate, which may include but is not limited to:
 - further proficiency testing;
 - an assessment of the laboratory;
 - suspension of all or part of the laboratory's approval/accreditation.

Annex 1: Approved Laboratory Program Application Form

Application for listing as an approved laboratory for testing carried out as part of AQIS export certification

(for microbiological testing laboratories only)

| | |
|--|--|
| Laboratory Name NATA Accreditation number (if applicable) NATA site number (if applicable) | |
| Laboratory Address | Laboratory Postal Address |
| Name of person responsible for laboratory approvals/QA e.g. Laboratory/QA manager | Email, phone and fax numbers at laboratory |
| Name of person responsible for laboratory testing | Email, phone and fax numbers at laboratory |
| Names of NATA signatories for Approved Methods (if applicable) | Email, phone and fax numbers at laboratory |
| Approved testing methods intended to be used under the Approved Laboratory Program (see right). Full names of all methods with associated references should be included eg <i>E. coli</i> Petrifilm, AOAC Official Method 998.08 | Type of products tested e.g. meat surfaces, grab sample of raw meat pieces or other products (please specify). |
| <i>(Note: list may be attached if not sufficient space)</i> | |
| List of AQIS registered meat establishments using this laboratory for the required tests in the past 12 months | |

I*(insert name and position)* wish to apply for the above named laboratory to be listed as an approved laboratory for the purpose of testing meat and meat products (including environmental samples) using the approved methods listed above.

- I confirm that this laboratory has been accredited by NATA to perform the tests listed above in accordance with NATA requirements (strike out if not appropriate).
- I further declare that this laboratory will grant AQIS access to the laboratory, including access to laboratory methods and records relevant to the above tests for the purpose of

review of the accreditation system. This includes granting access to importing country reviewers as nominated by AQIS;

- I grant AQIS access to NATA records relevant to its accreditation in relation to testing of export meat and meat products, including, but not limited to, results of assessments by NATA (strike out if not appropriate).
- I grant AQIS access to records of proficiency testing results held by the laboratory or by the proficiency testing provider.
- I agree that this laboratory will report relevant test results to AQIS at the same time that they are reported to the client (AQIS registered meat establishment), this will be documented in the laboratory QA manual;
- I understand that I am required to participate in proficiency testing programs to demonstrate competency and that the frequency of proficiency testing is determined by NATA or AQIS. I will inform AQIS of any non-conforming test results and provide documentary evidence of any corrective action taken;
- I understand that failure to meet any of the requirements for approval may result in suspension or withdrawal from the list of approved laboratories.

I have attached:

- Evidence of accreditation by NATA for the approved methods listed above (if applicable).

Signature:(signature)

Date:(Day Month Year)

Signed:(Insert name and position)

Witness;(signature)

Date:(Day Month Year)

I understand that giving false or misleading information is a serious offence.

Applications should be sent to: Approved Laboratory Program, Food Exports, Food Division, Biosecurity Services Group, GPO Box 858, Canberra ACT 2601 or MID.OpsCord@aqis.gov.au

Applications will be held in the strictest confidence and comply with the Information Privacy Principles in the Privacy Act 1988 (Commonwealth)

Annex 2: Requirements for on-plant Laboratories

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1 Introduction

The Australian Quarantine and Inspection Service (AQIS) ensure that all aspects of export inspection in Australia are delivered to a prescribed standard. This includes ensuring that appropriately validated procedures are used for monitoring performance of the system, particularly with regard to microbiological testing.

AS ISO/IEC 17025-2005 “General requirements for the competency of testing and calibration laboratories” details requirements for laboratories carrying out testing. Currently, laboratories undertaking *E. coli* and *Salmonella* carcass testing are required to be accredited by a recognised accreditation body (NATA) and hence adopt the requirements of AS ISO/IEC 17025-2005. While all laboratories carrying out microbiological testing are encouraged to obtain NATA accreditation, AQIS recognises that for certain laboratories this may be difficult. An example may be on-plant laboratories undertaking limited testing, such as rapid tests for *E. coli* O157:H7.

The following document details the minimum requirements under AS ISO/IEC 17025-2005 for laboratories undertaking testing carried out as part of AQIS certification and applies only to laboratories that are not NATA accredited.

1.1 Scope

This document applies to non-NATA accredited laboratories undertaking microbiological testing as part of AQIS certification and in some cases testing for pathogens that is part of customer requirements. In addition, other testing that is part of a company’s approved arrangement (AA) and that impacts on the final quality or safety of the product produced must be carried out in a laboratory that meets the requirements of this document.

2 Management Requirements

2.1 Organisation

- 2.1.1 The responsibilities of key personnel in the organisation that have an involvement or influence on the testing activities of the laboratory must be documented in the company’s Approved Arrangement.
- 2.1.2 The laboratory must have documented arrangements that ensure that laboratory personnel are free from undue internal and external commercial, financial and other pressures or influences that may adversely affect the quality of their work. The laboratory manager must have direct access to the highest level of management and should not be answerable directly to the production manager.
- 2.1.3 The laboratory must provide adequate supervision of all of its staff.

2.2 Management system

- 2.2.1 The laboratory shall establish, implement and maintain a (laboratory) quality manual that details policies, systems and procedures necessary to ensure the quality of the test result.
- 2.2.2 The quality manual shall contain detailed work instructions for all methods used by the laboratory including quality control procedures.
- 2.2.3 The laboratory shall establish and maintain a procedure for the control of all documentation relating to the management system, including procedures for approval and document changes.
- 2.2.4 The laboratory shall have a policy and procedure for selection and purchasing of supplies that ensures that the quality of the test results is maintained.
- 2.2.5 The laboratory manager shall participate in plant management meetings and actively seek feedback on performance.
- 2.2.6 The laboratory shall have a written policy and procedure that must be implemented when any aspect of the testing does not conform to the procedures.
- 2.2.7 The laboratory must record non-conformities and corrective actions taken. This must include an assessment of the significance of the non-conformity on the analytical results.
- 2.2.8 Internal audits of the laboratory management system shall be undertaken annually.

2.3 Control of records

- 2.3.1 The laboratory shall establish and maintain procedures for the identification, safe storage and disposal of records.
- 2.3.2 The laboratory shall retain records of original observations and other records required to establish an audit trail. This must include calibration records and test reports.
- 2.3.3 Where mistakes in recording are made such mistakes must be crossed out, not erased, and initialled by the person making the correction.
- 2.3.4 Calculations and data transfer must be subject to appropriate checks.

3 Technical Requirements

3.1 Personnel

- 3.1.1 Laboratory management shall ensure the competency of all staff based on appropriate education, training, experience and/or demonstrated skills as appropriate.
- 3.1.2 The laboratory shall maintain current job description for all staff involved in testing.

- 3.1.3 Laboratories shall maintain records of relevant staff competencies including training.

3.2 Accommodation and environment

- 3.2.1 Laboratory management shall ensure that the environmental conditions in the laboratory do not compromise the validity of the test results and monitor conditions as required.
- 3.2.2 The laboratory must be effectively separated from the rest of the plant and the work flow designed to minimise cross-contamination.
- 3.2.3 Access to the laboratory must be restricted to authorised personnel.
- 3.2.4 Laboratories shall be well lit, air-conditioned and free from draughts (i.e. no opened windows).
- 3.2.5 The laboratory must be kept clean and free from dust.
- 3.2.6 A dedicated hand wash station must be provided.

3.3 Test Methods

- 3.3.1 The laboratory must use appropriate methods for the analysis being performed. **Note: approved methods must be used for testing that is part of AQIS certification** (see Approved Methods Manual available on the AQIS web site).
- 3.3.2 Methods must be documented in sufficient detail to provide clear, stepwise instructions to staff and should contain the following information:
- Unique identification;
 - Scope (including reference to standard methods if appropriate);
 - Type of sample that can be tested using the method (e.g. carcase swab);
 - Apparatus and equipment required including performance requirements (e.g. incubator running at 37 ± 1 °C);
 - Reference standard and quality control required;
 - Environmental conditions required and any stabilisation required (e.g. tempering of molten agar prior to use);
 - Description of procedure including labelling of samples, check of equipment to be performed, recording of observations, calculation of results (including a worked example) and reporting; and
 - Acceptance and rejection criteria for relevant aspects of the analysis (e.g. sample receipt).

3.4 Equipment

- The laboratory must be furnished with all equipment necessary to ensure the validity of the test results.
- Equipment must be capable of achieving the accuracy required by the relevant test being carried out (including routine quality control tests).
- All equipment must be uniquely identified.

- All equipment must be appropriately calibrated and any correction factors relating to calibration must be applied.

3.4.1 pH Meter

- pH meters must be accurate to 0.1 units.
- Calibration of pH meters must be undertaken daily when in use using two buffers, generally pH 4 and pH 7.
- Records of calibration must be kept that provide an auditable link to specific batches of media and tests.

3.4.2 Balances

- The balances must meet the accuracy requirements of the test being carried out.
- Three yearly external calibrations must be performed by an accredited certification body.
- Zero points are to be checked each time the balance is used.
- A single point near the capacity of the balance must be checked monthly.
- Repeatability readings must be carried out every 6 months.
- Appropriate reference masses must be available and must be re-calibrated initially after 3-years and subsequently every 6 years.
- Records shall be kept of all calibration data.

3.4.3 Thermometers

- Records shall be kept of all calibration data

Liquid-in-glass

- Reference thermometers must have an appropriate range and graduation and must be calibrated every 10 years.
- Working thermometers must be checked at ice point and in the working range on commissioning.
- Ice point checks or checks in the working range of all working thermometers must be carried out every 6 months.
- For monitoring of critical equipment working thermometers must be externally calibrated every 5-years.

Digital devices

- Digital reference thermometers must be calibrated annually
- For monitoring of critical equipment working thermometers must be calibrated every 2-years
- All working thermometers must be checked against the reference thermometer at the temperature of use every 6 months..

3.4.4 Incubators and Temperature Controlled Equipment

- Operating temperature of all incubators and temperature controlled equipment (freezers, refrigerators etc) must be monitored daily when in use.

- Monitoring results must be recorded and readily available to staff. It is recommended that records are displayed on the equipment where possible.
- All equipment shall be checked for spatial temperature variation on commissioning and after major repairs.

3.4.5 Autoclaves

- Autoclave temperature profile must be checked annually.
- Load profiles for typical loads must be determined.
- Timer must be checked every 6-months
- Records shall be kept of autoclave cycles, including load type, temperature and time.
- Indicators shall be used with each load to demonstrate correct operation.

3.4.6 Pipettors

- Accuracy and precision must be checked every 3-months at the volume delivered. As a guide an acceptability criterion of $\pm 2\%$ can be used.
- Sterile blanks should be periodically included during testing to verify sterility.

3.5 Sampling

- 3.5.1 The laboratory shall have appropriate documentation and procedures for the collection, transportation, receipt, handling, protection, storage and disposal of samples.
- 3.5.2 The laboratory shall monitor sample conditions that may affect the validity of the test result, e.g. time between collection and analysis, temperature on arrival etc.

3.6 Assuring the quality of test results

- 3.6.1 The laboratory shall have appropriate documentation and procedures for monitoring the validity of test results including media quality control and verification of test results.
- 3.6.2 The laboratory shall have a documented procedure for handling, preparation and use of control cultures. Control cultures for each test being performed must be included with each batch of tests or run at least daily. Control cultures should be used at 10-100 colony forming units per tested weight or volume.
- 3.6.3 The laboratory shall participate in external proficiency testing programs for all analytes where available, at a minimum frequency of once every 6 months.

3.7 Reporting of results

- 3.7.1 The laboratory shall have appropriate documentation and procedures for the reporting of results. This must include procedures for reporting results directly to AQIS at the same time that they are reported to the establishment

management or submitting laboratory in the case of laboratories confirming tests results.

3.7.2 All reports issued by the laboratory should have as a minimum the following information:

- Unique report number
- Laboratory/Establishment name and AQIS number
- Date of report
- Identification of the method used
- Identification of any ambiguous conditions associated with the test
- Date of receipt of the sample including unique sample identification
- Date of testing
- Test results including units e.g. CFU/cm²
- Name and signature of the person authorising the report

3.7.3 If requested the laboratory can include in the report as needed opinions and interpretations. Justification for these opinions and interpretations shall be documented by the laboratory.